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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,118	07/02/2003	Darlene M. Dreon	0125-UTL	3886

38706 7590 09/19/2005

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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/612,118

Applicant(s)

DREON ET AL.

Examiner

Shirley V. Gembeh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 01/02/04, 01/05/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beinlich et al., US 2005/0124689 A1, Kapoor et al US 2002/0068100 A1, Bland et al.,

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US 2002/0192310 A1, Miller et al., US 6,426,632 B1 Seiki et al., US 2003/0086981 A1 and Horrobin US 6,479,544 and 5,120,760.

Beinlich et al., teach a non-alpha tocopherol (claim 1, 32) as a method for treating and or ameliorating (at page 1 § 0002) premenstrual syndrome at page 1 § 0003 , comprises less than 10% alpha tocopherol (claim 1) at page 10 § 0101, wherein the tocopherol composition is selected from beta, delta and gamma tocopherols (claims 4- 5, 8) at page 2 § 0016, where gamma tocopherol is at least 60% (claim 6) at page 2 § 0017, at least 90% gamma tocopherol (claim 7) at § 00017, wherein the metabolites gamma-carboxyethyl hydroxyl chroman (claim 9) at page 2 § 0016.

Beinlich et al., also teach as in claim 17 a mineral at page 17 § 0182, a nutritional portable product (claim 29) (food bars and or tablets (claim 25)) at page 17 § 0185 also in the form of a tablet at page, a C-reactive protein (CRP) as in claim 42 at § 0124, comprising 100-500 mg gamma tocopherol at page17 § 0188 and about 30 % delta tocophero at page 2 § 0017(claim23).

Beinlich et al., also teach, inflammatory biomarker white blood cell at page 17 § 0180 and tocotrienol as gamma-CEHC at § 0228.

Kapoor et al teach as claims 1 and 11 an omega 3- poly-unsaturated fatty acid at page 2 § 0029, wherein the medicament consisting of zinc (claim 18) a mineral as in claim 17, which is a divalent ion as in claim 19 at page 1§ 0007 and 0065. Kapoor also teaches flavonoids as bioflavonoids at page 1 § 0007 to treat premenstrual syndrome at page 1 § 0002.

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Bland et al teach at page 6 § 0074 omega-3-poly unsaturated fatty acid as in claim 1, wherein the compound consist of Magnesium as in claims 17-21, at page 12 § 0083, (claim 23), a flavonoid quercetin at § 0083 as in claims 22, and 33. Bland also teaches as in claim 37 administering hormonal contraceptive at § 0083.

Miller et al teach administering at least 200 mg (column 24 line 44) of hesperetin as in claim 23 a flavonoid at column 18 line 65. Miller however did not teach the combination as claimed by the applicant. It is however obvious to the one of ordinary skill at the time the invention was made to add quecertin as it is already known to the skilled artisan as these compounds are used to promote health in individuals by inhibiting hormones such estrogen and also reduce inflammation.

Seiki et al teach claims 1-3 wherein the glycerin fatty acids are not less than 10 % as in claim 1, and 5 % as in claim 2 at page 4 § 0036 and not less than 2 % as in claim 3 at § 0034. Hence no more than about can be interpreted to be at least within the percent range given but no more than, wherein the symptom is fatigue at page 6 § 0059.

Horrobin teaches (claim 12) wherein the omega-6-poly unsaturated is less than 10% at column 4 lines 5-10, wherein the omega-3-poly unsaturated is DHA as in claim 13 at column 4 line 32 ('760) and the ratio of DHA to EPA to be between 1:1 and 20:1 at column 2 line 22 ('544). However, Horrobin did not per se teach omega 6 but showed that essential fatty acids are of general formula n-3 or n-6.

The Beinlich reference teaches one skilled in the art at the time the invention was made would have obtained the same result as claimed by combining together the

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teachings taught by Kapoor, Bland, Miller, Seiki and Horrobin to treat PMS or PMDD related symptoms. One of ordinary skill in the art would have known that administering to a female a non-alpha tocopherol or metabolite thereof together with an omega-3-poly-unsaturated fatty acid would reduce the symptoms of PMS or inflammation.

Additionally once a method or a compound composition is known it is within the skill of the artisan to determine the optimum range of amount needed as in claims 1-3, 6,7, 14, and 23 for the treatment of the patient. Hence, the severity of the said medical conditions vary from patient to patient therefore the medicaments will be varied as well. Miller teaches the suitable ratios that are well within the instant claimed invention at columns 21 and 22.

Therefore one of ordinary skill in the art would have been motivated to combine the teachings of Beinlich, Kapoor, Bland, Miller, Seiki and Horrobin and expect a successful result in the treatment of premenstrual syndrome.

It would have been obvious to the one of ordinary skill in the art to combine the teachings of the above cited prior art, have a kit that comprises of a non-alpha tocopherol or a metabolite thereof, an omega 3 poly-unsaturated fatty acid, with flavonoid and a mineral in plurality of tablets with direction of use. One of ordinary skill in the art would have known to put the different components in separate packages to treat PMS, PMDD as it is well known in the art that combinations of drugs/medicament is now very popular gives synergistic effect when combined in the treatment of a medical problem associated with medical problems such as PMS, PMDD and the likes.

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Claims 46-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruzzese, US 5,776,978, Beinlich et al., US 2005/0124689 A1, Miller et al., US 6,426,632 B1, Bland et al., US 2002/0192310 A1 and Mechoulam et al US 5,618,955

Bruzzese teaches treating inflammation with tocopherols and omega 9 poly-unsaturated fatty acids at § 0002 also teaches omega 3 as in claim 71.

Beinlich et al., teach a non-alpha tocopherol (claim 46) as a method for treating and or ameliorating (at page 1 § 0002) premenstrual syndrome at page 1 § 0003 , comprises less than 10% alpha tocopherol, wherein the tocopherol composition is at least 60% as in claim 47. Beinlich et al., also teach the symptom occurring during late luteal phase at § 0090 in a woman (human-female) of her menstrual cycle (claims 56, 58, 64 65, 69 and 70), a C-reactive protein (CRP) as in claim 53 at § 0124. Beinlich et al., also teach, inflammatory biomarker white blood cell at page 17 § 0180 and tocotrienol as gamma-CEHC at § 0228.

Miller et al teach administering hesperetin as in claim 48-49, 72 a flavonoid at column 18 line 65. Miller however did not teach the combination as claimed by the applicant. It is however obvious to the one of ordinary skill at the time the invention was made to add quecetin as it is already known to the skilled artisan as these compounds are promote health in individuals by inhibiting hormones such estrogen and also reduce inflammation.

Bland et al teach at page 6 § 0074 omega-3-poly unsaturated fatty acid as in claim 61, wherein the compound consist of Magnesium as in claims 50-52 and 73, at page 12 § 0083, a flavonoid quercetin at § 0083 as in claims 48, and 49.

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Mechoulam et al teach an eicosatrienoic acid that is in its cis-configuration as claim 47 at column 4 line 13 for the treatment of inflammation.

Although, individually the above cited reference did not per se teach the symptom dysmenorrhea and the combination of quercetin and hesperetin. However, dysmenorrhea is a pain and a symptom associated with inflammation while experiencing PMS or PMDD occurring usually in the pelvic area from severe cramping and bloating, mood swings and the like.

One of ordinary skill in the art would combine the teachings of Bruzzese with that of Beinlich et al, Miller, Bland and Mechoulam, since these medicament have been used in ameliorating or reducing PMS syndromes in female patients.

One of ordinary skill in the art would have been motivated to combine the cited prior art to reduce pain in a female suffering from PMS and expect a successful result in doing so, since in the art it is well documented the use of tocopherols, omega 3, 6 or 9 poly unsaturated fatty acids in combination with flavonoids, minerals to react in synergy and give relief to the patient.

As combined, the references would have resulted in the claimed invention. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious over the cited art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SVG
8/25/05

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